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Attorney Docket No. 015280-212200US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
On

TOWNSEND and TOWNSEND and CREW LLP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Salahuddin et al.

Application No.: 10/087,882

Filed: March 1, 2002

For: ANTIBODIES AGAINST HUMAN

HERPES VIRUS-6 (HHV-6) AND

METHOD OF USE

SECOND SUPPLEMENTAL REISSUE DECLARATION UNDER 37 C.F.R. § 1.175(a)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We, Syed Z. Salahuddin, Dharam V. Ablashi, Steven F. Josephs, Carl W. Saxinger, Flossie Wong-Staal and Robert C. Gallo, declare as follows:

1. We are citizens and residents of the United States of America.

- 2. We have assigned the entire right, title, and interest in U.S. Patent No. 6,054,283 to the United States of America as represented by the Secretary of the Department of Health and Human Services.
- 3. We are the original inventors of the invention described and claimed in the above-identified United States Letters Patent and the claims added by the above referenced reissue application, for which invention we seek a reissue of the aforesaid Letters Patent.
- 4. We do not know and do not believe that the invention was ever known or used in the United States of America before our invention thereof.
- 5. We have reviewed and understand the contents of the amended claims as presented in the accompanying response to the Office Action mailed on March 5, 2003 for the above-referenced application.
- 6. We acknowledge the duty to disclose information of which we are aware and which is material to the examination of this application for reissue of the original Letters Patent in accordance with 37 C.F.R. § 1.56.
- 7. We believe the original patent to be partly inoperative in that the original patent claims less than we have a right to claim in the patent. Our invention is generally directed to methods of detecting human B lymphotropic virus (HBLV) infection. Claims 2 and 3 of the issued patent recite two distinct methods by which HBLV infection can be detected. Claim 2 describes a method of detecting HBLV infection by contacting an antibody that specifically binds to an antigenic molecule from HBLV with a biological sample and detecting the antibody-antigen complex. Claim 3 describes a method whereby the antibody-antigen complex is detected by a western blot.

The methods recited in claims 2 and 3 are not the only methods of detecting HBLV infection. For example, HBLV infection can be detected by immunoassays that detect antibodies that specifically bind to HBLV as described at column 10, lines 59-67 and column 13, lines 3-6 of U.S. Patent No. 6,054,283.

- 8. We believe that the unduly constrained literal scope of the claims prior to this amendment arose from insufficient communication between us and patent counsel as a result of which the patent counsel lacked full appreciation of the scope and function of the invention. (These errors in claiming less than we had a right to claim arose without any deceptive intention on our part.)
- 9. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| Full name of first inventor: | Syed Z. Salahuddin | |
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| Full name of third inventor: | Steven F. Josephs | |
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| Full name of fourth inventor: | Carl W. Saxinger | |
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| Full name of fifth inventor: | Flossie Wong-Staal | |
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TOWNSEND and TOWNSEND and CREW LLP

By:_____

Ded. (ursigned)

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Application No.: 10/087,882

Filed: March 1, 2002

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- 3. We are the original inventors of the invention described and claimed in the above-identified United States Letters Patent and the claims added by the above referenced reissue application, for which invention we seek a reissue of the aforesaid Letters Patent.
- 4. We do not know and do not believe that the invention was ever known or used in the United States of America before our invention thereof.
- 5. We have reviewed and understand the contents of the amended claims as presented in the response filed on February 6, 2003 for the above-referenced application.
- 6. We acknowledge the duty to disclose information of which we are aware and which is material to the examination of this application for reissue of the original Letters Patent in accordance with 37 C.F.R. § 1.56.
- 7. We believe the original patent to be partly inoperative in that the original patent claims less than we have a right to claim in the patent. Our invention is generally directed to methods of detecting human B lymphotropic virus (HBLV) infection. Claims 2 and 3 of the issued patent recite two distinct methods by which HBLV infection can be detected. Claim 2 describes a method of detecting HBLV infection by contacting an antibody that specifically binds to an antigenic molecule from HBLV with a biological sample and detecting the antibody-antigen complex. Claim 3 describes a method whereby the antibody-antigen complex is detected by a western blot.

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SALAHUDDIN, Syed A. et al. Page 4

PATENT

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